

[BILLING CODE 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS-0055-P]

RIN 0938-AT52

Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would adopt a modification to the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs by requiring covered entities to use the Quantity Prescribed (460-ET) field for retail pharmacy transactions for Schedule II drugs. The modification would enable covered entities to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, in the HIPAA retail pharmacy transactions. We believe this modification is important to ensure information is available to help prevent impermissible refills of Schedule II drugs, which would help to address the public health concerns associated with prescription drug abuse in the United States.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-0055-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov> . Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0055-P,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0055-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

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SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the Department of Health and Human Services (HHS) to adopt standards for electronic health care administrative transactions conducted between health care providers, health plans, and health care clearinghouses. In January 2009 (74 FR 3295), the Secretary adopted the National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007 (hereinafter referred to as Version D.0) for the following retail pharmacy transactions: health care claims or equivalent encounter information; referral certification and authorization; and coordination of benefits. As

discussed later, a technical issue with Version D.0 necessitates a modification of the requirements for the use of this standard.

A. Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills

The HHS Office of the Inspector General (OIG) conducted a study of Medicare Part D payments for Schedule II drugs that were billed as refills in 2009. Schedule II drugs are of particular interest to regulators because of the public health issues associated with their use and the potential for misuse and abuse. Schedule II drugs are defined, in part, by the Controlled Substances Act (CSA) as those with a high potential for abuse, with use potentially leading to severe psychological or physical dependence (21 U.S.C. 812(b)(2)). The CSA prohibits the refilling of Schedule II drugs; however, in some cases partial fills are permissible. Partial fills of Schedule II drugs were previously allowed only in limited circumstances, including where a pharmacist had less quantity on hand than the prescribed amount of medication, the prescription was for a patient in a LTC facility, or a patient had a terminal illness.¹

Based on the data from the study, the HHS OIG issued a report in September 2012 titled “Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills,” which analyzed all of the 2009 program year prescription drug event (PDE) records for refills of Schedule II drugs.² The OIG analyzed 20.1 million records for Schedule II drugs and identified refills according to the numeric values in a particular data field—the Fill Number (403-D3)³ field. The OIG concluded that the Medicare Part D program had inappropriately paid

¹The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to the NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by CARA.

²Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

³National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007, defines the Fill Number Field as “403-D3”.

\$25 million for 397,203 Schedule II drug refills and that long-term care (LTC) facility pharmacies billed for 75 percent of such refills. OIG stated that the Medicare Part D plan sponsors should not have paid for those drugs because federal law prohibits Schedule II drug refills, and concluded that “[p]aying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street.”⁴

PDE records are claim summary records submitted by prescription drug plan sponsors to CMS for every prescription filled by a provider for a Medicare Part D beneficiary. PDE records contain data elements from prescription drug claims. One of those data elements is the Fill Number (403-D3) field. The Version D.0 implementation specifications require that a “0” be entered in that field for a new prescription and that the number be sequentially increased by 1 for each refill. For purposes of its report, the OIG methodology specified that any value greater than zero is considered a refill.⁵ Accordingly, where it found the value in the Fill Number (403-D3) field in a PDE record to be greater than zero, the OIG concluded that the PDE record was a refill for a Schedule II drug, though it acknowledged, given the fact that LTC facility pharmacies were allowed to dispense partial fills (where less than the full amount prescribed is dispensed) for Schedule II drugs under certain conditions, that it was possible some LTC facility pharmacies may have incorrectly billed partial fills of these drugs as refills.

In its written response to the OIG report⁶, the Centers for Medicare & Medicaid Services (CMS) noted its concern that the OIG’s strict interpretation of PDE data did not support the OIG’s findings. CMS believed that the OIG’s findings were based in part on a misinterpretation

⁴ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 13
<https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

⁵ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 6
<https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

⁶ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 17
<https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

of Schedule II drug partial fills dispensed to LTC facility residents as refills. The NCPDP maintains a work group, known as WG9 Government Programs Medicare Part D FAQ Task Group (hereinafter referred to as Task Group), designed to guide federal pharmacy programs on NCPDP standards. CMS made an inquiry to the Task Group, noting that although the OIG report appeared to misinterpret partial fills dispensed to patients in LTC facility pharmacies as refills, it was not aware of any means by which such a pharmacy could distinguish partial fills of a controlled substance prescription for billing purposes without using the Fill Number (403-D3) field. This inquiry resulted in NCPDP submitting Designated Standard Maintenance Organization (DSMO) change request #1182⁷ to update the pharmacy standard.

In August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule titled "Health Insurance Reform: Standards for Electronic Transactions" in which the Secretary adopted procedures to maintain existing HIPAA standards, modify existing HIPAA standards, and adopt new HIPAA standards. This August 2000 final rule also established a new category of organization, entitled "Designated Standard Maintenance Organization (DSMO)." DSMOs which are accredited by the American National Standards Institute (ANSI), are responsible for maintaining the standards adopted under HIPAA and are required to receive and process change requests proposals for new standards or the modification of existing standards. Individuals, entities and organizations that believe an adopted standard requires modification may submit change requests to the appropriate DSMO. The change request must be accompanied by a documented business case that supports the recommendation. The DSMO, through committee structure, will then review the request and notify the appropriate Standard Development Organization, in this case, whether it approves or rejects the modification request. Approved

⁷https://www.ncdp.org/NCPDP/media/pdf/OESS_request_20121115.pdf

recommendations are then forwarded to National Committee of Vital Health Statistics (NCVHS) by the DSMO. NCVHS reviews the recommendation and, through its own committee structure, determines whether or not to formally recommend adoption of the modification by the Secretary of HHS.

DSMO change request #1182, was done in response to CMS request to the Task Group if there was a way to appropriately use the current NCPDP D.0 standard to distinguish partial fills of a controlled substance prescription from refills in LTC facility pharmacy claims. The Task Group replied in a letter⁸ to CMS advising that the Version D.0 implementation specification does not support the OIG's findings regarding the use of the Fill Number (403-D3) field, further stating that the industry uses the Fill Number (403-D3) field to represent the fill number (that is, the amount actually dispensed) and not necessarily the refill number. The Task Group indicated it would work on a clarification to avoid further misinterpretation, advising CMS that the NCPDP would recommend changes to the standard to allow Version D.0 to specify the conditional use of the Quantity Prescribed (460-ET) field, which is not used in the claim billing transaction, to indicate the actual quantity prescribed in the transmission of the claim, which would make data available to validate whether there are inappropriate fills in excess of the quantity prescribed. The NCPDP effected this change in its November 2012 publication of Version D.0, which required the use of the Quantity Prescribed (460-ET) field when claims for Schedule II drugs are submitted to Medicare Part D. NCPDP's modification to the standard addressed Medicare Part D only, therefore HHS has not adopted the 2012 version because it is limited to Medicare Part D only. Therefore, HIPAA covered entities may not use it to remain in compliance with HIPAA. HHS believes that by modifying the requirements for the use of the

⁸https://www.ncdpd.org/NCPDP/media/pdf/OESS_request_20121115.pdf

NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, all covered entities, not just entities submitting Medicare Part D transactions, to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, in the HIPAA retail pharmacy transactions.

B. National Committee on Vital and Health Statistics (NCVHS) Recommendation

The National Committee on Vital and Health Statistics (NCVHS) was established by statute in 1949; it serves as an advisory committee to the Secretary and is statutorily conferred a significant role in the Secretary’s adoption and modification of HIPAA standards. On June 21, 2013, the NCVHS wrote to the Secretary that it agreed with the NCPDP’s recommended plan to allow Version D.0 to specify the conditional use of the Quantity Prescribed (460-ET) field in a republished Version D.0 with an explanation in the Editorial Corrections section and a change to the Version D.0 Editorial Document.⁹ The NCVHS indicated that with this change, “data will be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed, a concern raised in a September, 2012 report from the HHS Office of the Inspector General.” In light of the opioid crisis, HHS believes in the importance of a targeted modification of the Version D.0 standard, to ensure the availability of data to indicate whether Schedule II drugs are being inappropriately filled, and we are proposing requirements for the use of Version D.0 to specify that covered entities must treat the Quantity Prescribed (460-ET) field as required for retail pharmacy transactions.

C. Congressional and Administration Actions in Response to the Opioid Crisis

During the last decade the nation has experienced worsening issues with opioid addiction and overdose deaths, prompting various Congressional and Administration actions. For

⁹ To review the recommendation, see <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/130621lt1.pdf>.

example, the Comprehensive Addiction and Recovery Act (CARA) (Pub. L. 114-198) was enacted on July 22, 2016, and amended the CSA to allow a pharmacist to partially fill a prescription for a Schedule II controlled substance if: (1) such partial fills are not prohibited by state law; (2) a partial fill is requested by the patient or prescribing practitioner; and (3) the total quantity dispensed in a partial fill does not exceed the quantity prescribed. Partial fills of Schedule II drugs were previously allowed only in limited circumstances, including where a pharmacist had less quantity on hand than the prescribed amount of medication, the prescription was for a patient in a LTC facility, or a patient had a terminal illness.¹⁰

We believe CARA's implementation will yield an upsurge of partial refills, which supports the need for this proposed modification. That view is echoed in a May 31, 2017 letter the NCPDP sent to the DEA, which said "[w]ith implementation of the CARA partial Fill Provision, the potential exists for a significant increase in the number of occurrences of a prescription for a Schedule II controlled substance being partially filled."

At the President's direction, the Secretary of HHS declared a nationwide public health emergency to address the opioids crisis on October 26, 2017.¹¹ The President also declared a nationwide public health emergency pertaining to the opioid crisis and directed the heads of executive departments and agencies to use all lawful means to exercise all appropriate emergency and other relevant authorities to reduce the number of deaths and minimize the devastation the drug demand and opioid crisis inflicts upon American communities. To address the crisis, HHS also announced a 5-Point Strategy calling for better: (1) addiction prevention, treatment, and recovery services; (2) data; (3) pain management; (4) targeting of overdose

¹⁰The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to the NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by CARA.

¹¹<https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf>

reversing drugs; and (5) research¹². The requirements proposed in this rule would support one of HHS's top opioid strategic priorities calling for better data, which could ultimately result in reduced drug supply.

II. Provisions of the Proposed Regulations

A. Proposed Modification to the Requirements for Use of the Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, NCPDP

As discussed earlier, covered entities inconsistently reflect partial fills and fill numbers in the HIPAA retail pharmacy transactions that utilize Version D.0 because the currently adopted Version D.0 does not permit covered entities to use the Quantity Prescribed (460-ET) field. As a result, stakeholders cannot reliably discern from transactions data when a Schedule II drug has been partially filled or refilled. To remedy this problem, we are proposing to require, under the circumstances explained later, the Quantity Prescribed (460-ET) field in the August 2007 Version D.0 (the version currently adopted by HHS) to be treated as required. These changes would enable covered entities to clearly distinguish partial fills and fill numbers in the HIPAA retail pharmacy transactions, which would support and improve the Administration's and the health care industry's data collection and research efforts by, among other things, enabling policymakers, health care researchers, and other health care stakeholders that monitor the volume of opioids billed to health plans across the country to correctly identify partial fills in claims and prior authorization transactions. By facilitating accurate assessments, policymakers would be able to establish more effective controls and other measures to prevent inappropriate, or even illegal, prescribing of Schedule II drugs.

¹²<https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

In this proposed rule, we would require the Quantity Prescribed (460-ET) field in the August 2007 Version D.0 to be treated as a required field where the transmission uses the August 2007 Version D.0 standard for a Schedule II drug for the following three transactions: (1) health care claims or equivalent encounter information; (2) referral certification and authorization; and (3) coordination of benefits. We would modify the regulations at §§ 162.1102, 162.1302, and 162.1802 to apply the new requirements. To ensure that the proposed definition of “Schedule II drugs” mirrors the DEA definition, we would specify that the term has the same meaning as the definition of that term at 21 CFR 1308.12.

To be clear, our proposal would not modify the presently adopted Version D.0 in any way. Rather, it would require covered entities to treat a field in Version D.0 differently than the Version D.0 implementation specification requires. We further want to make clear that this proposal also does not propose to adopt the 2012 publication of Version D.0. There, the NCPDP changed the Quantity Prescribed (460-ET) field designation from “not used” to “situational,” and the situational circumstance is “[r]equired for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only.” By applying only to transactions involving Medicare Part D claims, the 2012 publication would not cover a huge swath of HIPAA covered entities and therefore we believe our proposal would yield much greater benefit than if we were to adopt that 2012 publication.

We also note that the NCPDP has issued a subsequent publication, the October 2017 Telecommunication Standard Implementation Guide, Version F2 (Version F2), where, among many other unrelated changes, it revised the situational circumstance to specify an even broader use of the Quantity Prescribed (460-ET) field as “required only if the claim is for a controlled substance or for other products as required by law; otherwise, not available for use.” We note

that although the NCVHS on May 17, 2018 recommended adoption of Version F2 to the Secretary, we are not presently proposing to adopt it because, it would delay the ability for covered entities to accurately capture partial fills of Schedule II drugs. In addition, given the many other significant changes it would require of covered entities, we believe it requires further evaluation. We are, however, committed to continuing to work with stakeholders to update as appropriate the HIPAA standards used for retail pharmacy transactions, and we are carefully considering the NCVHS's recommendation.

In addition, given the public health emergency caused by the opioid crisis and the urgent need to find ways to yield data and information to help combat it, we believe it is more appropriate for us to take this narrow, targeted approach that would not be overly burdensome to covered entities and can be accomplished quickly.

B. Compliance Date

We propose to revise § 162.1102 to reflect that covered entities would be required to be in compliance with the modification to the requirements for the use of Version D.0 in retail pharmacy transactions 180 days after the effective date of the final rule.

We believe these proposed requirements are a modification to an implementation specification, which is defined at 45 CFR 160.103 as a specific requirement or instruction for implementing a standard. Section 1175(b)(2) of the Act specifies that the compliance date for a modification to a standard or implementation specification cannot be sooner than 180 days after the date the modification is adopted. A modification is considered to be “adopted” on the date it becomes effective in the **Federal Register**, which in this case would be 60 days after its publication in the **Federal Register**. Because we believe it is important for this modification to be implemented as soon as statutorily permissible, we are proposing that covered entities would

be required to comply with the modification 180 days after the date the modification is adopted in a final rule (to be clear, this would be 240 days following the date of publication of a final rule).

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We would consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we would respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of

available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

Covered entities inconsistently reflect partial fills and fill numbers for Schedule II drugs in retail pharmacy transactions that utilize Version D.0 because Version D.0 does not permit covered entities to use the Quantity Prescribed (460-ET) field. As a result, stakeholders cannot reliably discern from transactions data when a Schedule II drug has been partially filled or refilled. To help understand the economic burden of this issue, we refer back to the previously mentioned 2012 OIG report which estimates that pharmacies inaccurately billed \$25 million worth of partial fills as refills in 2009 paid by the Medicare Part D program. The OIG also expressed concerns about the possibility of these inappropriately dispensed Schedule II drugs being resold on the street.¹³ As noted previously, CMS noted its concern that the OIG's strict interpretation of PDE data did not support the OIG's findings. CMS believed that the OIG's findings were based in part on a misinterpretation of Schedule II drug partial fills dispensed to LTC facility residents as refills, however, these findings are helpful as a starting point for this estimate. The White House Council of Economic Advisers estimates that opioids abuse exacted a cost of \$504 billion in 2015 and contributed to a significant number of prescription and illicit drug overdose deaths.¹⁴ Furthermore, and as previously discussed, the Secretary declared a public health emergency to combat the opioid crisis.

¹³ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

¹⁴ <https://www.whitehouse.gov/opioids/>

For this analysis we leverage the historical cost and benefit data from the study conducted to support the Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards proposed and final rules (73 FR 49742 and 74 FR 3295, 3296, respectively) (hereinafter referenced as the study). The impact analysis for this proposed rule utilizes the historical cost estimates derived from the study across covered entities. The final estimate provided an overall cost of \$38 million to fully implement the then-new requirements of the 2007 Version D.0 for chain pharmacies (73 FR 49772). Since this is a very narrow, targeted modification that is limited to requiring covered entities to use the Quantity Prescribed (460-ET) field of the already adopted Version D.0, we anticipate the aggregate costs to be minimal. We expect minor system and implementation expenses, which would consist of modifying software configurations, updating business processes, and minimal personnel training. We further believe the investments to adopt this modification and update existing systems have the same cost variables as the adoption of this current D.0 version. We used these same considerations from the January 16, 2009 final rule (74 FR 3296), to formulate our assumptions on implementing system upgrades, and staff training costs. While it is difficult to determine aggregate costs across the industry, we believe system costs for this modification would require limited IT resources, training, and changes to business processes, and have estimated that this modification would cost between 1 to 5 percent of the original estimated cost, or between \$380,000 and \$1,900,000. The study also estimated a maximum upgrade fee cost of \$1.08 million per year for independent pharmacies (73 FR 49772). This results in an estimated cost for this modification of \$10,800 to \$54,000 per year in service fees across all independent pharmacies.

Pharmacies would benefit from using the Quantity Prescribed (460-ET) field because it would facilitate better monitoring of Schedule II drugs for over- or inappropriate

prescribing. By virtue of this more robust data that we believe could be used to help avoid audits and incorrect payments, we estimate that large pharmacy chains could save up to \$500,000 per year, while , while smaller chains could save approximately \$100,000 per chain. Therefore, this could yield a total 10-year benefit of up to \$10 million, and that does not account for the value of the time pharmacists and pharmacy technician staff who process these claims also might save.

We believe health plans and their associated pharmacy benefit managers (PBMs) would also incur minimal cost since most have existing hardware and software platforms capable of using this field with their current technology and networks. Thus, we expect this modification to have a similarly minimal cost impact of between 1 and 5 percent of the original implementation costs. The study originally estimated the total cost to implement the 2007 Version D.0 for plans and PBMs to be a maximum of \$10.6 million for the industry (73 FR 49773). Thus, we estimate that the total cost for this modification for health plans and PBMs to be between \$106,000 and \$530,000.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. We anticipate that the Quantity Prescribed (460-ET) field requirements would result in a reduction of overprescribing and inappropriate prescribing of Schedule II drugs, and also reinforce our commitment to lowering

overall health care costs by reducing administrative burden and improving the quality of health care.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate the great majority of retail pharmacies are small businesses as defined by the Small Business Administration's (SBA) definition of having revenues of less than \$7.5 million to \$38.5 million in any 1 year. The SBA defines a size threshold in terms of annual revenues for pharmacies as \$27.5 million; we estimate that 95 percent of retail pharmacies have revenues below \$27.5 million or are nonprofit organizations and are therefore considered small entities. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities because the Quantity Prescribed (460-ET) field requirements are a minor modification for covered entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we continue to define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies

assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. We believe this proposed rule would have no consequential effect on state, local, or tribal governments or on the private sector in excess of that threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We believe that since this proposed rule would not impose substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule is expected to be an EO 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule’s economic analysis.

We have assessed the anticipated costs and benefits of this proposed rule and estimate that it would reduce operating costs for standard pharmacy transactions, remove inefficiencies and ambiguities, and facilitate better monitoring of Schedule II drugs.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 162

Administrative practice and procedures, electronic transactions, health facilities, health insurance, hospitals, incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 162 as set forth below:

PART 162 – ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d-1320d-9), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, sec. 105 of Pub. L. 110-233, 122 Stat. 881-922, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note), and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

2. Section 162.1102 is amended by adding paragraph (d) to read as follows:

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

* * * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE AFTER PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the Quantity Prescribed (460-ET) field must be treated as required where the transmission meets both of the following:

- (1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.
- (2) Uses the standard identified in paragraph (b)(2)(i) of this section.

3. Section 162.1302 is amended by adding paragraph (d) to read as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE AFTER PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the Quantity Prescribed (460-ET) field must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

4. Section 162.1802 is amended by adding paragraph (d) to read as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the Quantity Prescribed (460-ET) field must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

Dated: December 18, 2018

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2019-00554 Filed: 1/30/2019 8:45 am; Publication Date: 1/31/2019]